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March 29, 2004

Food and Drug Administration  
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, D.C. 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403®(6) (21 U.S.C. 343r (6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma LLC, 22N. Main Street. Newport, NH 03773, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the label:

Text of Claims: Supports Heart and Prostate Health\*

Name of Ingredients Subject to Claim: Flaxseed concentrate, Pumpkin seed oil and Zinc

Name of the Supplement: Men's FiProFLAX

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma LLC has substantiation that the statement is truthful and not misleading.

Sincerely,

Jill Bunn  
Technical Manager

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